

COMMENTARY

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'Read this and be safe!' Comparison of regulatory processes for communicating risks of personal care products to European and South African consumers

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Abstract

Background: Most personal care products (PCPs) contain hazardous ingredients, but current legislation in the European Union (EU) and South Africa (SA) does not require these to be labelled as hazardous products. Instead, ingredients must only be listed on containers to inform consumers of potential hazards. We assessed whether current legal strategies provide the means for effective risk communication (RC) mechanisms for PCPs in order to protect consumers' health and the environment.

Results and conclusions: RC strategies used in developed countries are not necessarily better compared to developing countries despite the existence of extensive legislation in the former. Socio-cultural factors, scientific literacy and language differences are key reasons why the current ingredient lists on PCP labels are not an effective RC strategy. The assumption is that consumers will interpret the risks of these ingredients by conducting a risk assessment for their personal context. Realistically, the following risk mitigation measures should be implemented in developed and developing countries to reduce the public's potential exposures to hazardous substances: substitute hazardous ingredients with less hazardous; provide accessible mechanisms for consumers to comprehend RC measures; delete the exception clause in the EU Regulation on Classification, Labelling and Packaging (CLP); apply clear mandatory labels where PCPs health risks are clearly illustrated; and increase enforcement of legislation. The high incidence of fragrance allergies caused by PCPs is one example illustrating how current legal measures in the EU and SA fail to protect consumers and the environment from hazardous exposures. Therefore, efforts must be made to improve legally required RC measures.

Keywords: Classification and labeling; Consumer protection; Cosmetics; Developing and developed countries; Hazardous substances; Personal care products; Risk communication

Background

Consumers are tasked with risk decision making - whether they know it or not - every time they purchase personal care products (PCPs), since many ingredients in PCPs pose health threats and have the potential to contaminate the environment. That is, consumers must use the hazard data provided on the label and make a risk assessment based on their (and their family's) own exposures, uses and physiology. The mechanisms, however, for making these

decisions are unknown to the general public, complicated and inadequate. That is, inadequate to make informed risk decisions and inadequate to effectively prevent short- and long-term health effects as well as contamination of the environment. In this article, we analyze the complexity and problems for consumers in the European Union (EU) and in South Africa (SA) to use current hazard information on PCPs labels for assessing risks.

PCPs include toiletries, skin care products, hair care products, decorative cosmetics, and perfumes. Although this article refers to PCPs to provide a broader understanding of the products discussed, the term 'cosmetics' is used in both European and South African legislation

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to refer to PCPs - that is, *cosmetic products* and *cosmetics* in the European Cosmetics regulation (EC 1223/2009) [1] and *cosmetics* in South African legislation (SA Act 39 of 2007 [2]). These products are readily available for use on the body and in the mouth for cleansing, perfuming, correcting body odors and conditions, beautifying, protecting, promoting attractiveness, or improving or altering a person's appearance. PCP production and use is ever increasing globally. In 2010, sales of PCPs in the EU were over 66 billion Euros, which is a third of the global PCP market (www.cosmeticseurope.eu). Although recent data on sale numbers of PCPs in SA are available in a country report (<http://www.euromonitor.com/beauty-and-personal-care-in-south-africa/report>), accessing these statistics is rather prohibitive for researchers as the cost is 1,800€. Given the wide use and availability of PCPs, consumers need to both be informed about potential hazards to human health and the environment from these products, as well as to know how to reduce and prevent risks.

The hazards posed by PCPs depend on the inherent (eco-)toxicological properties of the ingredients. A hazard is defined as 'a possible source of danger' [3], described through standardized classification and labelling as presented by the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) [4,5]. Yet the level of risk caused by PCPs is dependent on consumers' exposures. If there is no exposure to a dangerous substance, there is no risk. For some products containing hazardous chemicals, such as pesticides, a complex and detailed risk assessment outlining the potential health and environmental risks is conducted by scientific experts and presented with the registration application for these products [6]. In the case of PCPs, however, the producers conduct a safety evaluation and the hazards are presented in the ingredient lists on the labels. Conducting of a risk assessment is thus left to the consumer. However, studies have indicated that consumers perceived health or environmental risks of PCPs very differently compared to the scientifically assessed risk from exposures to PCPs [7-9]. This raises the question as to whether consumers' human rights are being violated by requiring consumers to make a risk judgment without the scientific background or level of literacy required for this task. We, therefore, argue that appropriate and effective risk communication (RC) mechanisms are needed to correctly inform consumers. Further, the means for consumers to understand this information should be provided and required through various legal instruments. In this article, we assess whether the type of information provided on PCP product labels to consumers in the EU and SA is effective to promote risk reduction decision making and whether the information is presented in a manner that is comprehensible by consumers who are heterogeneous

in their languages, literacy levels, technical literacy levels, and visual literacy levels. With global trade in PCPs resulting in products being distributed widely, it is important to compare and contrast RC mechanisms used. This article concludes with recommendations on how to improve on the comprehension of risk information among diverse population groups.

Discussion

Hazardous substances in personal care products

PCPs contain ingredients, such as fragrances, colors, solvents or preservatives, many of which are hazardous substances or hazardous mixtures with various adverse effects. Even some natural substances added to these products can be sensitizers or irritants (e.g., fragrances; [9]). Some examples of health effects associated with common ingredients used in PCPs are endocrine disruption [10-13], allergies [9,14-19], associations with asthma [10] and birth defects [20]. Although, not all consumers develop obvious negative effects when using PCPs and benefit from these products, some persons suffer considerable health problems from the hazardous ingredients in PCPs. Unfortunately, there are no estimations about the number of unreported cases. Contact allergy can be linked relatively easily to the application of certain PCPs containing sensitizers. Approximately 6% of the general population suffers from contact allergy due to exposures to PCPs [21]. Other health effects are more difficult to make a causal link with certain PCP ingredients. Therefore, most of the publications about negative effects of PCPs tend to focus on contact allergies, mainly caused by fragrances, dyes or preservatives, which skews the overall picture of related effects [22-24]. Studies sampling the general population with patch tests revealed that fragrance allergies to the standard set of fragrances (i.e., fragrance mix I) is an increasing clinical problem in many Northern and Southern hemisphere countries [25]. Furthermore, some of the preservatives in PCPs (e.g., parabens, formaldehyde), which have a biocidal action to protect the products against microbial contamination, are known to be contact allergens and are found at higher concentrations in products than needed indicating that they are 'over preserved' [21].

Carcinogens, mutagens and substances toxic to reproduction (CMR substances) are in principle prohibited according to the Cosmetics Regulation 1223/2009 [1], but there are exceptions for these substances where 'their use has been found safe' by the Scientific Committee for Consumer Safety (SCCS) [1]. Mutagens (such as *m*-phenylenediamine), carcinogens (such as carbomer) or substances toxic for reproduction (such as cyclo-methicone) were listed in formulations of PCPs [26], but they usually are below the concentration thresholds for labelling and classification of the mixture thus exposing uninformed consumers. Butylphenyl methylpropional,

classified as suspected of damaging fertility or the unborn child (C&L Inventory [27]), is a frequently used masking agent present in products sold in retail shops where the exact percentage in the final product is not disclosed. Furthermore, Hutter and colleagues [28] identified synthetic musks in blood of young healthy adults which came from cosmetic products applied to the skin. In the USA, a correlation was observed between the use of PCPs containing estrogens (e.g., placenta or synthetic hormones such as estron or estradiol) and increased breast cancer incidence [29]. In another study in the USA, endocrine disruptors, such as phthalates, parabens or nitrosamines, were identified in PCPs [30]. Assessing the human health risks posed by dangerous ingredients in PCPs is an important public health concern because of the high exposures resulting from PCP direct application to the human body surface both intentionally and frequently [31]. Some PCPs are diluted with water during application (*rinse-off* products), such as in the case of shampoo or soap, whereas others are applied undiluted onto the skin or hair (*leave-on* products), as is the case with lotion or deodorant, leading to higher exposures than *rinse-off* products. Users tend to use varied amounts of PCPs and several products at the same time which leads to a further increase of the exposure. Furthermore, application of PCPs on children potentially poses a greater risk of exposure to hazardous chemicals [32,33]. Therefore, exposures and exposure risks will vary considerably for consumers using PCPs [34]. RC measures consequently must address these varied exposures and exposure patterns, as well as differences in consumer populations (e.g., children, culturally diverse).

The frequent use of PCPs also raises concerns of environmental contamination, especially water sources, given the large quantities of products released into sewage systems and leaching in landfills [35]. Conclusive research on the extent of dangers for aquatic environments caused by PCPs is still scarce [36-39]. Extensive and continuous discharge of PCPs into the water compartment, however, gives reason for concern as some ingredients are biologically active compounds similar to pharmaceuticals [36]. Some PCPs are readily degraded; others are persistent [40]. For example, many studies have been conducted for synthetic musks highlighting their presence and stability in the environment and their (eco-)toxicological effects [41-43]. Cocamidopropyl betaine and lauryl alcohol, classified as dangerous for the aquatic environment, are frequently used as ingredients of PCPs such as shampoos. The amounts entering the aquatic compartment can be substantial making the relevant concentrations measurable, as is this case with the ingredients OTNE or HHCb [44]. As the number of ingredients in PCPs is massive, the task of assessing these risks is daunting and often beyond budget allocations, particularly in developing countries. Furthermore, the situation

and research needs in developed countries compared to developing countries are impacted by different climatic conditions, different technical levels of water treatment and/or various portions of indirect reuse of water. Thus, prevention of hazardous PCPs entering the environment is the best strategy.

RC legal instruments

Having outlined the need for better communication of PCP health and environmental risks to consumers, we review in this article current RC mechanisms and how these should be improved.

RC mechanisms in general for PCPs

Legal regulations for RC should bridge the gap between (eco-)toxicological data generated by experts and risk perceptions of non-experts. Ideally, products posing no risks would not require any RC process. Yet, as long as PCPs pose a residual risk, the legal requirements should be adequate to ensure that consumers are informed and are able to understand the information provided in order to make informed choices. RC is the process through which individuals are informed about potential hazards and risks for risk mitigation decision making and management, often with the intention of provoking safety behaviors [3,45-48]. The process of communicating risks is not static, nor are there universally agreed upon approaches. Over the past 25 years, RC has evolved in developed countries as RC practitioners continued to identify more effective strategies. In 1995, Fischhoff listed these stages, each building on the former, as (1) all practitioners needed to do was make sure the statistics were right, (2) all practitioners needed to do was present the statistics, (3) all practitioners needed to do was explain what the statistics meant, (4) all practitioners needed to do was show that similar risks had previously been accepted, (5) all practitioners needed to do was illustrate that the risk is good for those exposed, (6) all practitioners needed to do was treat those exposed nicely, (7) all practitioners need to do is make those exposed to the risk partners, and (8) all practitioners need to do is incorporate all of the above stages [49,50]. The more recent literature on RC indicates that it should be a two-way process - that is, a process that involves consultation with and participation by the general public/consumers [3,46]. This could be seen as falling under Fischhoff's seventh stage. In developing and low-middle-income countries like SA, however, the RC process has not evolved and tends to be at Fischhoff's stages 1 and 2 - that is, risks are communicated through a top-down approach (one-way communication), or risk information is just presented (i.e. listed on the label) [46]. In the EU, the recognition of consultation and participation is referred to in several documents rather than implemented in practice. This is particularly

the case with PCP labels and results in the EU paying lip service to Fischhoff's stage 7. The reality is that two-way RC is costly and time consuming. Thus, the challenge is to move from policy to practice in order to protect consumers.

There exists an array of guidance on risk and hazard communication which influences country-specific legislation. PCP risk information is currently communicated to consumers differently and with different standards depending on country-specific legislation. Our intention is not to describe the legal instruments in detail, but rather to highlight some essential elements needed for labeling of PCPs to be an effective RC mechanism. The OECD guidance on RC for chemical risk management [51], for example, determines various types of risk situations where RC is recommended. The situation for PCPs corresponds to the so-called 'routine RC', where the 'risks are well known to scientists, risk managers are aware of the potential consequences and few uncertainties remain'. This implies that a proactive communication with the general public should be embarked on [3].

In order to develop appropriate RC mechanisms for PCPs, these need to incorporate several key issues and address key questions for each. These are:

- (i) *Residual risk*: Which risk is an unavoidable residual risk? Which risk is acceptable based on the use context? Who should decide which residual risk is tolerable/acceptable (government officials, manufacturers, scientists, NGOs or consumers)? How did policy interpret the complex scientific information to develop legal standards?
- (ii) *Type and presentation of information*: How is the information presented and where? Who determines what is put on a label? Is the design of a product consistent, or does it look harmless, even if it contains hazardous substances? How are diverse cultures and literacy capabilities addressed? What mechanisms are put in place to aid the understanding of the information?
- (iii) *Receivers*: Is there a culture of reading labels amongst consumers? Is the language of the label technical or easily understood by all consumers? Does the understanding lead to a safer handling of the products? [45]
- (iv) *Messengers*: Who is providing the information? How do consumers view/respect this information provider? Are they trusted? [45]
- (v) *Aims*: How important is the safety for consumers in the RC process? How important is the protection of the environment? What are the economic and other interests?
- (vi) *Feasibility*: Who is responsible for the control? Who pays for it? Are there effective penalties

that lead to a better conformity with the legal requirements in the future? Who monitors the relevance and updating of the information provided?

Examples of legal RC mechanisms

EU PCP ingredients in the EU are regulated like other substances by the relevant chemical legislations (see below REACH [52] and the EU Regulation on Classification, Labelling and Packaging (CLP) [53]). When these ingredients, however, are used in cosmetic products, they are regulated under the Cosmetics Regulation which does not require risk assessments but a 'safety evaluation' by a competent safety assessor [1]. This evaluation mainly considers irritation and contact allergy, while other possible effects on human health or the environment need not be assessed [54-56]. Considering the required administration of vast amounts of data for all chemicals, better coordination of these regulations would go a long way to promote effective PCP risk management [57]. Ingredients of PCPs are good examples to show how difficult it is to regulate chemicals through legal instruments such as REACH and respective product regulations. Manufacturers establish product safety according to safety assessments [58]. From a scientific perspective, it is generally not possible to prove a chemical to be 'safe'. Instead, it is only possible to indicate that no risk has been identified thus far. We, therefore, recommend the wording 'risk assessment' be used instead of 'safety evaluation'. On the other hand, causation between a chemical in a certain product linked to a specific health effect is difficult to prove. More than 1,300 hazardous substances are prohibited (e.g., lead and its compounds) according to the EU cosmetics regulation. A further 150 chemicals require exposure risk mitigation measures which means that they may only be used under certain conditions (e.g., formaldehyde or methanol in Annex III of the Cosmetics Regulation: list of substances which cosmetic products must not contain except subject to restrictions laid down; [1]). Currently the main RC mechanism for PCPs is the product label ingredient list listing names as specified in the INCI-List (Inventory and a Common Nomenclature of Ingredients employed in Cosmetic Products) [59]. A specific requirement in relation to PCP ingredient lists has been the '26 allergens rule' [60,61]. This is part of the cosmetics regulation and requires that 26 potential allergenic fragrance substances be listed on labels if they are present above 0.001 percent in 'leave-on' products (e.g., lotions) or above 0.01 percent in 'rinse-off' products (e.g., shampoos). The amounts are not indicated on the label and there are no maximum concentration limits for all of them. Consumers also receive information about shelf lives and specific safety

instructions for some products, such as hair dyes. Section 'Examples of ingredient lists from the EU and the USA' illustrates a hypothetical PCP ingredient listing commonly found on labels. The assumption is that consumers will evaluate these ingredient lists, identifying potential hazards, and assess which chemicals pose a risk for them personally. Then, after identifying these risks, based on their exposures and own health status, they will either not buy the product or implement an effective and scientifically proven risk mitigation strategy. These are onerous and unrealistic assumptions for consumers to execute. The '26 allergens rule' [60,61] is part of the cosmetic regulation and requires that 26 potential allergenic fragrance substances must be named on the labels if they are present above 0.001 percent in 'leave-on' products such as lotions or above 0.01 percent in 'rinse-off' products such as shampoos. The amounts are not indicated on the label and there are no maximum concentration limits for all of them.

Examples of ingredient lists from the EU and the USA

The following are the acceptable ingredient listing adapted from [62]:

1. Acceptable in the EU only. The following are the ingredients: aqua, alcohol denat., *Hamamelis virginiana*, sodium PCA, mel, *Prunus amygdalus dulcis*, *Paraffinum liquidum*, *Melaleuca alternifolia* oil, parfum, phenoxyethanol, methylparaben, propylparaben, limonene, linalool, cinnamal, alpha-isomethyl ionone, CI 17200, CI 42090
2. Acceptable in the EU and the USA. The following are the ingredients: aqua (water), alcohol denat., *Hamamelis virginiana* (witch hazel) extract, sodium PCA, honey (mel), *Prunus amygdalus dulcis* (sweet almond) oil, *Paraffinum liquidum* (mineral oil), *Melaleuca alternifolia* (tea tree) leaf oil, parfum (fragrance), phenoxyethanol, methylparaben, propylparaben, Limonene, linalool, cinnamal, alpha-isomethyl ionone, CI 17200 (red 33), CI 42090 (blue 1)

Cosmetic products need not be classified and labelled in accordance with CLP [53], even if they contain dangerous substances above the classification thresholds. In contrast, other consumer products, such as glue or varnish, are classified and labeled but not required to have the list of ingredients on their container labels. If, however, PCPs were classified and labelled in accordance with the CLP, many of them would require hazard pictograms on the label [26].

Many ingredients of PCPs are self-classified by producers resulting in the CLP entries in the Classification and Labelling Inventory being continuously updated. The

outcome is that final classifications of the products are not consistent yet. Recent self-classifications made by the majority of suppliers tended to be less severe [63] so that the final classification of some products will be less severe as described by Klaschka [26]. As some PCPs contain hazardous substances above the threshold for labeling, the EU legislators made this exception in the CLP Regulation. Otherwise, an exception would have been superfluous.

The registration of cosmetic ingredients, according to the EU chemicals regulation (Registration, Evaluation, and Authorization of Chemicals, REACH) [52], may lead to more publically available information. However, several waiving conditions will apply to quite a number of cosmetic ingredients, (e.g., fragrances). Therefore, it cannot be taken for granted that the data situation will improve for all PCP ingredients [64]. In addition, according to REACH, the chemical safety report does not need to consider the risks to human health from the use of cosmetic products ([52] Chapter 1 Article 14 5(b)). As a result, REACH will not significantly contribute to reducing the current lack of risk information for ingredients in PCPs. According to REACH, RC is required if existing communication mechanisms are not being implemented effectively [3]. In the situation of PCPs, it must be questioned whether consumers are supplied 'with sufficient information to handle chemicals and articles containing the most hazardous substances safely' ([3] Page 10). In this case, member states could decide to introduce RC instruments before a harmonized solution is agreed upon under REACH [3] and may be a prime opportunity to improve PCP RC.

SA As in many other countries worldwide, ingredient lists are legally required on PCPs also in SA, although the detailed requirements vary. Communicating the chemical hazards of PCPs tends to be more of a legalistic requirement rather than ensuring that consumers are able to protect their health and the environment from these hazards. In the South African National Standard on *Ingredient labeling of cosmetic products* (not yet promulgated into law), the purpose of ingredient labeling is cited as 'to ensure transparency to the consumer, to give adequate information about the product, and to avoid purchase of a product that contains an ingredient that the consumer does not wish to use' [62]. What is rather alarming is the reference that the label allows a consumer to avoid purchasing a PCP containing ingredients the consumer wishes not to use. Firstly, the onus is put on the consumer to have the knowledge of unwanted or hazardous ingredients, and secondly, the assumption is that all consumers can read PCP ingredient lists as a toxicologist or eco-toxicologist. Furthermore, transparency is not defined in this standard but the

assumption is that by listing the ingredients of a PCP on the label, the consumer will be able to make an informed decision and know whether to avoid exposure. The reality is that SA is more interested in exporting cosmetics to the EU and the USA indicated through the emphasis on using labeling to comply with EU and harmonized INCI nomenclature. SA is addressing this issue with PCPs by adopting legislation that requires labeling more consistent with the EU and harmonized INCI nomenclature (see 'Examples of ingredient lists from the EU and the USA' section; [62]).

Comparison of the situation in the EU and SA The 'guidance on the communication of information on the risks and safe use of chemicals' developed by the European Chemicals Agency (ECHA) in the context of REACH [3] offers a theoretical approach for chemical RC. The purpose of this document is to help Member States Competent Authorities to communicate chemical risks to the public. The approach proposes four steps: (1) Understand the issue; (2) Determine the communication needs; (3) Implement RC; and (4) Evaluate and review. These steps are a useful exemplary structure for the analysis of RC mechanisms for PCPs as is illustrated in Table 1. The first column shows the general actions for RC recommended

by ECHA. In the second column, we illustrate what the direct application of these recommendations for PCPs would look like. Columns three and four give a brief overview about the current situation in the EU and in SA in relation to the ECHA recommended steps. Step one requires that the issue is well understood by Member States Competent Authorities based on the scientific data in relation to PCP ingredients, although the data availability is not as straightforward as for other chemicals [54,57]. In steps two to four, there is a big discrepancy between the recommendations by ECHA and the actual situations in the EU and SA, illustrating that PCPs RC is not in line with ECHA recommendations.

Other countries In the USA, additional English common names are required in brackets to assist consumers with understanding complex ingredient names (see 'Examples of ingredient lists from the EU and the USA' section). However, analytical screenings found that the ingredient lists are not always complete, and phthalates and fragrances are often not properly listed [10]. The International Cooperation on Cosmetic Regulation (ICCR), an international group of regulatory authorities from Canada, EU, Japan and the USA, is attempting to promote

Table 1 ECHA recommended actions for RC and simplified comparison with current status in the EU and in SA

| ECHA recommended actions | ECHA recommended actions applied to PCPs | Current status in the EU | Current status in SA |
|---------------------------------------|--|---|---|
| Step 1: Understand the issue | Detailed knowledge about ingredients obtained by standard laboratory tests or computational models is needed for sound hazard and risk assessments. | (Eco-)toxicological data on ingredients are available to the producer, the Competent Authorities and the informed public. Producers test their products and consider them as safe. Various stakeholders have different interests. | Actions rely on the industry to adhere to self regulation. |
| Step 2: Determine communication needs | The public should be able to make informed choices. This implies the need for comprehensible RC mechanisms to consumers. RC should help to reduce the risk for man and/or environment to the unavoidable minimum. | Many substances are banned or restricted according to the Cosmetics Regulation. | Follows EU regulations. |
| Step 3: Implement RC | Legal regulations should lead to a high level of consumer safety and environmental protection. | The ingredients must be listed on the PCPs. 26 potential allergenic fragrances must be listed by name on the PCPs. PCPs need not be classified and labelled according to the CLP Regulation. No exposure estimation to humans is needed according to REACH. Safety evaluation is performed according to the Cosmetics Regulation. | Follows EU labeling. |
| Step 4: Evaluate and review | Authorities should enforce and control the implementation of legal instruments. They should control whether the intended goals of risk reduction were reached and evaluate consumer comprehension of risk information. If necessary, new ways of RC should be developed and implemented. | There are product spot checks by authorities, but the control of consumer comprehension and protection is not integral part of the official RC process for PCPs. Only some independent research groups conducted surveys. The environmental concentrations are reason for concern for some cosmetic ingredients. The numbers of patients with contact allergy and other negative health effects caused by ingredients of cosmetic ingredients are high. | Consumer comprehension of label information is not evaluated. There is no research on improving RC mechanisms for PCPs. |

Sources: [1,3,52,53,62].

global consumer protection collectively while minimizing barriers to international trade. The focus of this group is currently on safety assessment with three outcomes relevant for RC labelling of PCPs:

- The product is safe for the proposed use without restrictions.
- The product is safe with restrictions and may need specific warnings or precautions (risk reduction measures).
- The product is not safe.

The safety statement ICCR is considering to include on PCPs is

After analysis of all available information including formulation, toxicological profile of the ingredients and clinical reports, it is concluded that, according to the current state of scientific knowledge, product XXX is not expected to cause damage to the human health and can be marketed for the intended and foreseeable use as [insert product type] [65].

These initiatives of the ICCR focus more on promoting trade than ensuring consumer safety and environmental protection through appropriate RC mechanisms on the label that are comprehensible by the consumer. Nor are manufacturers required to identify hazardous substances through signal words, precautionary statements or pictograms as is the case with non-PCP hazardous substances (e.g., pesticides, industrial chemicals). Globally, there is a trend to harmonize labelling of products containing hazardous chemicals in order to promote trade. The assumption is that harmonizing labels will also promote effective RC.

Consumer comprehension of hazard information

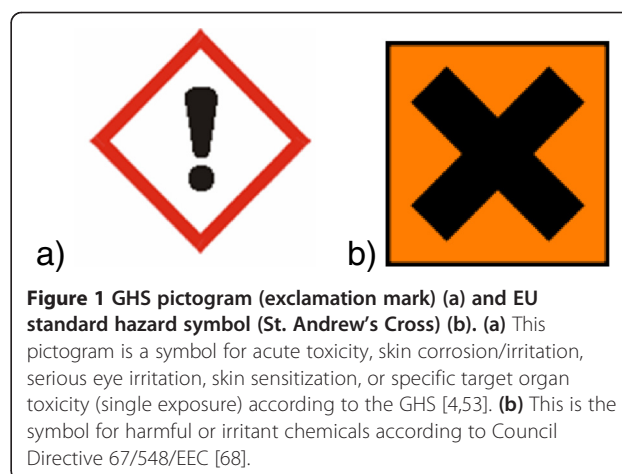
Consumers' right to know

The right-to-know movement of the 1970s began in the USA for the general public to have access to information in regard to hazardous chemicals, toxic emissions and placement of toxic factories, which became legislated under RC laws. This movement, however, has not extended to PCPs. We argue in this article that consumers have the right to be informed about the potential health and environmental risks posed by the PCPs they use. What is key is that consumers are not only provided with the relevant hazard information, but that the information is presented so that a non-scientific lay person can understand the information in order to make a risk assessment. If information provision is solely to protect the liability of industry or fulfill some legislated obligation, then the consumer is not being taken into account. In reality, many consumers are unaware of the potential

health effects (acute and chronic) and whether the use of these products is contributing to environmental contamination. Effective RC mechanisms are an important step to improved protection of the environment and the health of the consumers, but providing information is not enough. Consumers need to be able to understand the information and know what their options are.

In the European or South African legislation, there are currently no requirements for evaluating whether and how the general public understands the ingredient information on labels and how to use this information (see Step 4 in Table 1). It is therefore difficult to assess whether this type of RC leads to reduction of risks or not. The study by the European Agency *Communication on the Safe Use of Chemicals* revealed that the majority of the general public misinterprets pictograms of the CLP regulation [66,67]. For example, only 11% understood the meaning of the GHS acute toxicity pictogram frequently found on consumer products (GHS07; exclamation mark; Figure 1a) [66,67].

Other surveys assessing how hazard labels are perceived by the end-users revealed that pictograms are not well understood by the majority of the general public or the receivers as these are not intuitively obvious or cross-culturally transferable [45,66,69]. A South African study illustrated, through a mental models approach, how the scientifically intended meanings of pesticide label pictograms (based on risk assessment data) are mis-interpreted by farm workers [69,70]. For example, 36% of respondents did not know the UN Food and Agricultural Organization pictogram for *harmful* (i.e., the St. Andrew's Cross, Figure 1b), while 31% gave an incorrect interpretation (some definitions included 'for emergency, first aid kit, shows hospital, don't use, do not enter where this sign is shown' [69]. This study emphasized the point that RC mechanisms are not self-explanatory and do not take into account varying literacy levels and languages of end-users. For RC mechanisms to be understood as



scientifically intended, consumers need to be provided with the means to interpret this information [45].

As contact allergy is a common result of exposures to fragrances and because of the European '26 allergen rule', the comprehension and effectiveness of the declaration of fragrances on PCPs was analyzed in several studies. Noiesen conducted a survey to find out whether Danish patients with allergic contact dermatitis could use the names of the allergenic fragrances listed on the containers to prevent harmful exposures. One finding was that patients with lower educational levels found it difficult to read the names of the chemicals on the containers, despite being trained on the INCI names. Furthermore, only half of the interviewees trusted the correctness of the information in the ingredient lists [7]. This illustrates that either the public does not trust the source of the information and/or that a specific fragrance that is below the threshold for declaration on the product might still elicit symptoms. In Lysdal and Johansen's [8] survey with patients suffering from a fragrance contact allergy, most respondents said that 'a more clear labelling of the fragrance ingredients would increase their benefit'. Of the patients interviewed, 56% indicated that they identified fragrance appropriate products by trial and error, compared to 35% who used the ingredient lists. Nardelli and colleagues [71] illustrated how the names of the allergenic fragrances on products used by patients assisted dermatologists with identifying the causal allergens. Thus, scientifically trained persons are more likely to use ingredient lists as intended but not average consumers. Although, the '26 allergens rule' has its limitations, there are other products that do not require that fragrances be declared at all (e.g., paper or textiles) [72] and so this is at least a step in the right direction.

'Read this and be safe!'

The findings from the above studies illustrate that the general public are not all able to read the ingredient lists on the labels nor understand the implications of these in order to use the products in a low-risk manner. We postulate that they are not even aware that they are tasked with conducting risk assessments, risk control and risk management. Consumers not only lack access to adequate information to make these assessments and safety measures, but they also often lack the numeracy and health literacy skills required to understand the information. The situation for PCPs is further aggravated by consumers being misled about the product safety from the attractive containers, appealing messages promised by the cosmetic industry, and the lack of warning symbols [33,66,67]. These messages tend to make consumers trust the products and make them less aware that they might contain dangerous substances. However, in some countries, particularly developed countries where consumers

have access to risk information through the internet, risk perceptions towards PCPs might be changing. A recent survey among American female students revealed 'that nearly half of the respondents do not believe that the government adequately regulates personal care products (45.5%) and over half do not feel that they know all they need to know about the ingredients in the personal care products they use (62.5%)' [34]. In this study, only less than 5% were not at all concerned about health and environmental risks posed by PCPs.

The example of a hypothetical ingredient list in the 'Examples of ingredient lists from the EU and the USA' section illustrates that consumers not only need to understand technical jargon, but they also need to have a scientific background (and good internet access) to know what these chemicals are and what role they play in the product. The USA label requirement at least provides common names for the ingredients in brackets to assist consumers with ingredient identification. Generally, and particularly in low-to-middle income countries such as SA, consumers will not be able to use the ingredient listing for any meaningful risk decision making as a result of lack of noticing the information and lack of comprehension of the information [45,69,73]. Whether the general public in the EU is able to use these lists adequately is also questionable.

What consumers need for understanding ingredient lists

The list of ingredients on the containers of PCPs is a means for consumers (e.g., for consumers with allergies) to establish the hazard and then assess their personal risk. What is needed is a method for all consumers to quickly interpret the meanings without having to access other resources (e.g., the internet, phone help line or poison centre). Consumers are not a homogenous group, and yet with the advent of the GHS, there are more and more efforts to standardized RC mechanisms globally to enhance trade [45]. Legislating risk information on PCP labels presumes consumers have the basic skills to understand risk information. In order to understand and to know what to do with this information, a consumer, regardless if they are from the EU or SA, would require the following basic knowledge and skills:

Adequate literacy levels In order for consumers to know that the label is providing risk information they need to read [73]. Secondly, the consumer must be able to read the language of the label. For labels using pictograms or colour to express risk/toxicity information, visual literacy is required [46].

Knowledge of labels as a RC tool Consumers first need to know that a label is providing risk information to promote informed decision making. In some countries (e.g.,

SA), there is not a culture of reading labels [46,73]. Labels are rather seen as just providing the product name and use instructions. PCP labels are not user friendly as illustrated by the ingredient lists made up of technical names. Many consumers are also unaware that label ingredients are listed in order of volume of the total product.

Means to comprehend What mechanisms are available to consumers to understand PCP labels? For consumers in a medium to high socio-economic bracket they may have access to the internet. This is, however, not the case for the majority of consumers in SA. What guidance is available to read and understand the hazardous chemical ingredients and explain how this information should be used?

Motivation to comprehend There are several elements which play a role in consumers using a PCP label to inform themselves about the potential risks. These include (a) a culture of reading labels, (b) an awareness that they provide hazard information and the expectation to receive a personal benefit, (c) a previous history/experience of a PCP causing a health effect to oneself or another, and (d) the time to engage with the information. Time is an important factor in the motivation to comprehend or to not bother trying to comprehend label information. How much time would a person with higher/lower education level have to invest to be informed - for example, when buying a deodorant? How much time do consumers really invest to inform themselves? People who have suffered health effects from PCPs are more motivated to inform themselves about the risks and to seek out information on particular ingredients [7].

With the two following frequently used fragrance ingredients in cosmetic products, we provide examples of what should be known about the risk when applying such substances regularly to one's body surface. These two fragrance ingredients must be named on EU labels according to the '26 allergens rule' [60,61]:

- The first example, *Limonene* (CAS 5989-27-5), is found in shampoos, washing and cleansing products, 'air fresheners' and products other than PCPs where there are no legal requirements for declaration on the products. Limonene is classified and labelled as H226 (*Flammable liquid and vapour*), H315 (*Causes skin irritation*), H317 (*May cause an allergic skin reaction*), H410 (*Very toxic to aquatic life with long-lasting effects*) and must be labelled with three pictograms in the pure state (GHS02 (flame), GHS07 (exclamation mark), GHS09 (risk for the environment)). In addition, its oxidation products can have higher sensitizing potentials.
- The second example, *Hydroxyisohexyl-3-cyclohexene carboxaldehyde* (synonym: 4-(4-Hydroxy-4-

methylpentyl)cyclohex-3-enecarbaldehyde (CAS 31906-04-4), is classified as H317 (*May cause an allergic skin reaction*), H319 (*Causes serious eye irritation*), H412 (*Harmful to aquatic life with long-lasting effects*) must be labelled by the GHS07 (exclamation mark) pictogram in the pure state. In case the consumer suffers from a contact allergy she or he should know that a doctor calls this substance Lyral or HMPCC, whereas the INCI name Hydroxyisohexyl-3-cyclohexene carboxaldehyde is written on the products.

In theory, consumers should use this information to make their own risk assessments in relation to each ingredient, the synergistic effect of the ingredients and the cumulative effect from exposures to other products containing these ingredients. Not only is this a complex task for a consumer, but there is limited research as to the synergistic effect of two or more hazardous chemicals contained in one product. Also, toxicologists and ecotoxicologists are not able to do such a risk assessment ad hoc, as an exposure-effect assessment is required with the estimation of a safe exposure level. Thus, expecting a consumer to do this illustrates that current ingredient lists on PCPs are not a viable RC mechanism and may well violate the rights of consumers.

Consumers' risk perceptions

The concept of risk has a clear meaning in the technical sciences, but for consumers, the concept of risk is often confused with hazard, referred to as danger when translated into local languages, experience-related and persuaded by social communication [46,66,74,75]. Social and cultural factors, which are regularly swayed by media reports, peer and family influences and other communication mechanisms, have more of an impact on consumers' understanding of risk than legislation and scientific data [70]. Labels on PCPs, as a risk communication tool, have been developed based on a technical rationality of risk, to influence consumer product use behaviours. Consumer risk behaviours, however, are not persuaded by risk information only and without understanding the interaction between RC mechanisms and consumer risk perceptions, the label is further rendered ineffective [45,46]. For example, a study in several European countries showed the correlation between risk perception and safety behavior was low [66]. What needs to be taken into account is how risk perceptions influence the understanding of RC mechanisms and what consumers' perceptions are of the ingredient lists, hazards symbols (Figure 1a,b) and any other method used to communicate risks [45]. The question is whether current labelling is more for protecting the industry from liability rather than acting as an effective RC mechanism to consumers. This being the case,

alternative approaches to increasing label comprehension are required. Detailed analyses are urgently needed to assess whether consumers' (whether in EU or SA) risk perceptions correspond to the potential risks of hazardous substances in PCPs in order to improve on current RC mechanisms.

Recommendations for mitigating risks

PCP RC in general

Socio-cultural, scientific literacy and language differences are key reasons why the ingredient lists are not a satisfactory RC strategy for PCPs. The comparison of the situation in developed and developing countries illustrates that RC is not necessarily better in developed countries despite the existence of extensive legislation. There are several risk mitigation measures that should be implemented as an integrated management strategy rather than focusing on only one approach to improve the situation. For example, there are some proposals on how to reduce risks posed by fragrance allergens in PCPs [64]. An effective RC process should be transparent and easily understandable by all target groups. It should use simple and clear language [3]. Furthermore, consumers should not be required to conduct risk assessments. Rather, PCPs should be required to be registered and overseen by a regulatory body that is able to assess the risks for the local populations and ensure a safe product assortment. In the case of PCP ingredients where there is unacceptable uncertainty about the potential hazards, the precautionary principle should be applied. RC is not context neutral [45]. We suggest that legal instruments for regulating PCPs be structured so as to take into account the use context, literacy levels, formal education, cultural factors, etc. of the consumer when developing RC mechanisms. This would include regular surveys to find out in what way the users comprehend the information/mechanisms and whether their designs would need adjustments. In our opinion, this internal control ought to be an inherent element in the RC process as no hazard or risk communication mechanism will ever be inherently obvious to the consumer. Aiding comprehension needs to be an integral and legislated component of PCP legislation. In reality, risk communication mechanisms are not cross-culturally transferable. Thus in a bid to promote and minimize trade barriers, consumer health and safety will be compromised. Methods to promote comprehension could include printed information, websites and other electronic communications, surveys and focus groups, public presentations and discussions, education and training, press releases and media interviews and press conferences [3].

Reduction of dangerous chemicals in consumer products

The best way to reduce risk is to keep the residual risk as small as possible through reducing the amount of

hazardous substances in the product [32,76]. This should be the first step before using RC mechanisms as risk reduction measures. For example, allergen avoidance prevents the acquisition of contact allergy of healthy individuals in the general population and helps to reduce the occurrence of symptoms in sensitized persons.

Substitution of dangerous substances by less hazardous substances is not always easy, but should be the first priority [52,77]. CMR substances, for example, should not be present in any PCPs and the exceptions allowed in the Cosmetic Regulation should be deleted. In the case of PCP ingredients where there is uncertainty about the potential hazards, the precautionary principle should be applied and these ingredients should be limited. Where compliance and enforcement of legislation is problematic, particularly in developing countries, highly hazardous ingredients should not be allowed for use in PCPs. Hazardous substances should not be substituted by substances of similar hazards, such as isoeugenol derivatives as substitutes for isoeugenol, as this does not reduce the risks to consumers and the environment [78,79]. We postulate that stricter standards are needed for people who want to use less toxic products and for vulnerable populations such as babies and children, pregnant women [32,33], people with respiratory problems, allergic people, as well as malnourished and immune-compromised populations.

Labels

As has been illustrated, provision of an ingredient list is not adequate to inform consumers of potential risks. Labels need to spell out the risks. Mechanisms need to explain what the risk information on the label means, why safety behaviours are required and what these safety behaviours are. Boelhouwer and colleagues [80] illustrated in two US surveys that hazard and precautionary labels may improve risk communications. However, it is interesting to note that the OECD guidance document on risk communication for chemical risk management [51] does not mention labelling of products as a risk communication method.

A step towards a better RC would be to delete the exception clause in the CLP-regulation for cosmetic products and to apply the hazard labels also for containers smaller than 125 mL [26]. The intention would be that, with time, consumer preference for less hazardous products would lead to a shift to manufacturing of less hazardous PCPs. The CLP currently does not allow that containers of hazardous products look harmless. If the exception in the CLP Regulation were deleted, it would be legally required that the design of PCP containers should highlight the risk messages on labels and not attempt to detract from the risk messages.

The CLP Regulation allows for up to six precautionary (P-) statements on the labels of hazardous products.

P-statements would be a good addition to PCP labels for drawing consumers' attention to potential risks. When applying the classification criteria of the CLP Regulation to PCP formulations, several products would have to be labeled with hazard (H-) statements [26,63]. Each H-statement leads to a set of P-statements [53]. Table 2 illustrates examples of potential P-statements for some PCPs resulting from the respective H-statements. It is evident that some of the P-statements would not be realistic for the normal application of PCPs. For example, hairspray producers would have to cite on the label the recommendation '*Wash ... thoroughly after handling* (P264)' or '*Wear protective gloves/protective clothing/eye protection/face protection*' (P280). Also, the P-statement '*Avoid breathing dust/fume/gas/mist/vapours/spray*' (P261) would be difficult to apply to perfume. Furthermore, many consumers apply perfume to the skin which does not correspond to the P-statement '*IF ON SKIN: Wash with plenty of soap and water*' (P302 + P352). These examples indicate that some application patterns of PCPs are in contrast with the recommendations in the precautionary statements. A further problem with the P-statements is they lack enough detail to evoke the intended safety behavior. For example, '*wear protective gloves*' does not indicate what type of material the gloves should be made of. In countries such as SA where there are 11 official languages and low literacy levels amongst the consumer population, P-statements alone would not assist with increasing consumer understanding of risk [46,69]. Even if compliance of users with P-statements may be imperfect [81], it is better to provide risk information than none. Advice on how to reduce exposures would also aid consumers in risk reduction. Thus, rather than change behaviours, risk reduction should occur through replacing hazardous ingredients in products.

Pictograms

Adding pictograms, icons and symbols to PCP labels is another recommended addition. Comprehensibility testing of potential pictograms, however, should be conducted before any pictograms are legislated for use. For example, the GHS pictograms were not subjected to global comprehensibility testing prior to the development of the first purple book. Comprehensibility testing, based on the University of Cape Town's testing methodology, took place too late [82] as there was no option for changing or adapting these pictograms. The GHS building block approach does, however, allow for countries to add additional pictograms that are relevant for the country context [5]. We do not recommend introducing more pictograms with a global scope since pictograms are not cross-culturally transferable or intuitively obvious [69]. Research has shown that pictograms are not clearly understood by consumers - especially the GHS pictogram for acute

toxicity (Figure 1a) [4]. We recommend that a mechanism be put in place for countries to evaluate and upgrade legally binding pictograms to improve RC. We therefore support the plan proposed by ECHA to perform a new analysis by 2015 before mixtures will have to be labeled with the new GHS pictograms [66]. The question of cross-cultural comprehension of pictograms as scientifically intended is illustrated by whether these are understood in the same way by an illiterate South African farm worker as by a Finnish professor. Importantly, misinterpretations of label information can even increase the health risk [69]. To reduce misinterpretations, we recommend clear hazard statements on the label with precautionary advice. We also recommend that any pictograms or icons used on labels have the meaning printed in clear and concise words underneath.

As an additional RC mechanism, we propose the mandatory use of special labelling for PCPs showing negative effects for skin (proposed GHS 17 in [64]) and eyes through clear and easily understandable pictograms, warning sentences or photographs after conducting comprehensibility research with the intended consumer audience. Risk information and the potential dangers could be written in big letters on the packages of PCPs, similar to the warnings found on tobacco products in the EU [83] and SA or the use of photographs of irritated skin or eyes (Figure 2), similar to the warnings on tobacco products in Australia [84]. Although there could be visual misinterpretation or the consumer may not know how to use the product while protecting themselves, these pictures would aid in addressing literacy issues. Of course, we suggest such warnings only on those PCPs containing hazardous substances, not on PCPs in general.

Instead of indicating hazards on the product containers through language and symbols, another useful RC strategy is the use of a standardized process for assessing and recommending the least hazardous products [86]. For example, the German Allergy and Asthma Association (Deutscher Allergie- und Asthmabund, DAAB), a non-governmental consumer organization, recommends products that fulfill stringent criteria and product testing. Producers of products that comply with these criteria of the DAAB are then allowed to use the DAAB logo on their labels (Figure 3). Consumers, taught the meaning of the logo, can use this process for reducing their exposures to hazardous ingredients.

Education and assistance for consumers

The reality is that no one RC method will be effective for all populations and an integrated approach, with several socio-cultural appropriate mechanisms, is needed. Easy access to information is vital so consumers do not need to search for what the information means. There are several methods for improving comprehension and scientifically

Table 2 Compilation of potential P-statements attributed to a small selection of cosmetic product formulas



| Product/pictograms and signal word/H statements | Corresponding P-statements |
|--|--|
| Hair spray  DANGER H225 Highly flammable liquid and vapour. H319 Causes serious eye irritation. | <i>Prevention:</i> P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking. P233 Keep container tightly closed. P240 Ground/bond container and receiving equipment. P241 Use explosion-proof electrical/ventilating/lighting/.../equipment. P242 Use only non-sparkling tools. P243 Take precautionary measures against static discharge. P264 Wash ... thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection/face protection. <i>Response:</i> P303 + P361 + P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical advice/attention. P370 + P378 In case of fire: Use ... for extinction. <i>Storage:</i> P403 + P235 Store in a well-ventilated place. Keep cool. <i>Disposal:</i> P501 Dispose of contents/container to ... |
| Oxidative hair dye formula  DANGER H314 Causes severe skin burns and eye damage. H318 Causes serious eye damage. | <i>Prevention:</i> P260 Do not breathe dust/fume/gas/mist/vapours/spray. P264 Wash ... thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection/face protection. <i>Response:</i> P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303 + P361 + P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. P304 + P340 If INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON Center or doctor/physician. P321 Specific treatment (see ... on this label). P363 Wash contaminated clothing before reuse. <i>Storage:</i> P405 Store locked up. <i>Disposal:</i> P501 Dispose of contents/container to ... |

Table 2 Compilation of potential P-statements attributed to a small selection of cosmetic product formulas (Continued)

After shave balm



WARNING

H361 Suspected of damaging fertility or the unborn child

Perfume



DANGER

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H411 Toxic to aquatic life with long-lasting effects.

Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P281 Use personal protective equipment as required.

Response: P308 + P313 IF exposed or concerned: Get medical advice/attention.

Storage: P405 Store locked up.

Disposal: P501 Dispose of contents/container to ...

Prevention:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P264 Wash ... thoroughly after handling.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P285 In case of inadequate ventilation, wear respiratory protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P304 + P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON Center or doctor/physician.

P321 Specific treatment (see ... on this label).

P332 + P313 If skin irritation occurs: Get medical advice/attention.

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

P362 Take off contaminated clothing and wash before reuse.

P363 Wash contaminated clothing before reuse.

P391 Collect spillage.

Storage: -

Disposal: P501 Dispose of contents/container to ...

Table 2 Compilation of potential P-statements attributed to a small selection of cosmetic product formulas (Continued)

Nail glue



WARNING

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

Prevention:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P264 Wash...thoroughly after handling.

P271 Use only outdoors or in a well-ventilated area.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P312 Call a POISON CENTER or doctor/physician if you feel unwell.

P321 Specific treatment (see ... on this label).

P332 + P313 If skin irritation occurs: Get medical advice/attention.

P337 + P313 If eye irritation persists: Get medical advice/attention.

P362 Take off contaminated clothing and wash before reuse.

Storage:

P403 + P233 Store in a well-ventilated place. Keep container tightly closed.

P405 Store locked up.

Disposal:

P501 Dispose of contents/container to...

Formulas were analyzed in [26] according to CLP [53].

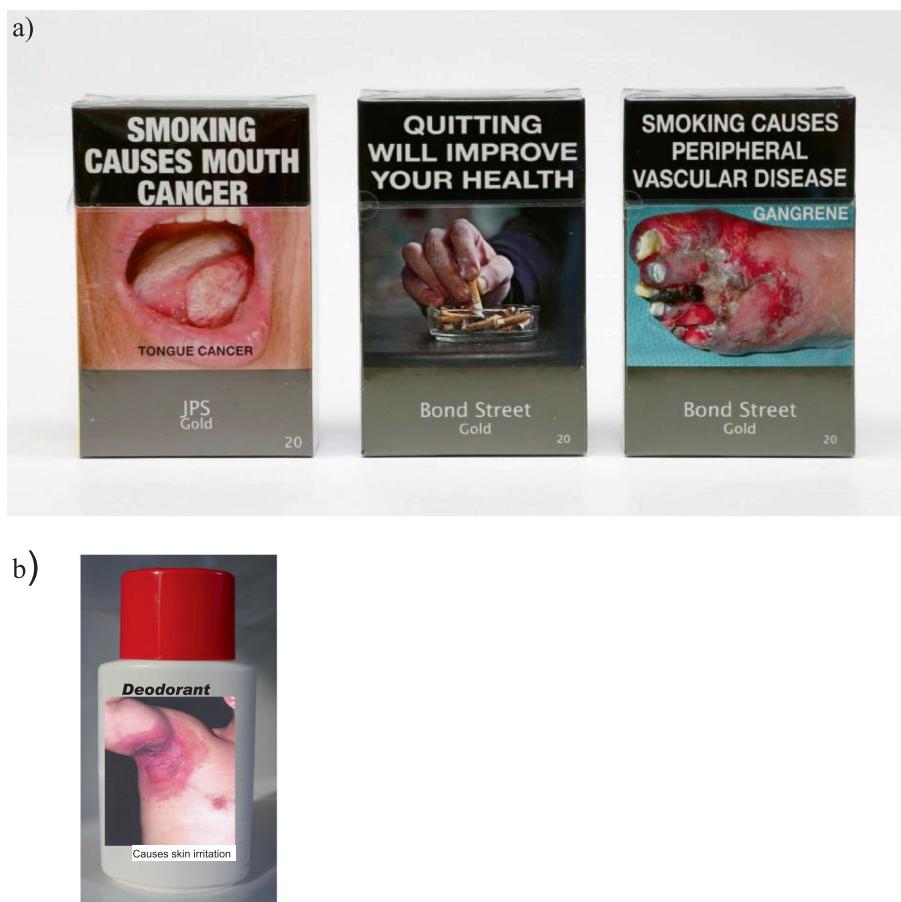


Figure 2 Examples of tobacco product labels and proposal for self-explanatory label for deodorant containing skin sensitizers or irritants. **(a)** Examples of tobacco product labels in Australia according to the Australian Tobacco Plain Packaging Bill [84]. **(b)** Proposal for a self-explanatory label for a deodorant containing skin sensitizers or irritants. The photograph of the axilla shows a patient with severe contact allergy to fragrance ingredients in deodorants (photograph by P.J. Frosch published in [85]).

ntended understanding of the messages. These include teaching how to read a PCP label in primary schools, providing brochures and posters next to where PCPs are sold aiding consumers in reading labels, providing telephone numbers on labels to an independent helpline that can answer questions and including label reading/comprehension in popular media. People who use or are exposed to PCPs on a professional basis should receive sufficient training and physicians should provide at-risk patients with relevant information. Also, some companies (e.g., the German Cosmetic, Toiletry, Perfumery and Detergent Association [Industrieverband Körperpflege- und Waschmittel. IKW] and the European Cosmetics Association [COLIPA]) could provide detailed and useful information on their homepages, e.g., about the safety of products and the legislation (www.ikw.org, www.cosmetic-seurope.eu). People suffering from contact allergy to cosmetic ingredients can also find help in medical allergy centers. There is further help by several consumer organizations, besides the above-mentioned DAAB. For example, the

environmental organization *Bund für Umwelt und Naturschutz* (BUND) in Germany has developed an electronic app to identify PCPs with endocrine-disrupting ingredients (www.bund.net/toxfox). Most consumer organizations rely on the ingredient lists on the products. However, if the lists are incomplete [10,72,87], they are



Figure 3 The logo of the German Allergy and Asthma Association (Deutscher Allergie- und Asthmabund, DAAB). It serves as indicator for PCPs recommended by the DAAB for patients suffering from skin or respiratory problems.

not able to make a correct product evaluation. The work of consumer organizations can also improve RC and we recommend that they should be supported by national authorities.

Box: study highlights

The following are the highlights of this study:

- PCPs ingredient lists are not a suitable RC instrument for consumers in the European Union or South Africa, as they place too much responsibility on the consumer and are more beneficial to trade.
- EU guidance for RC is not implemented for PCPs. The exception clause for PCPs in the CLP Regulation does not go in line with a decent RC.
- The huge efforts of data collection for REACH and CLP should be used for the benefit for the consumers and the environment.
- The 'right to know' should also be applied to PCPs. As long as hazardous substances are present in PCPs, clear labels are needed for consumer information.
- Routine RC implies a proactive communication with the general public. Effective RC implies a combination of several RC instruments depending on the target groups.
- Independent controls are needed to control whether the aims of a RC instruments were achieved, leading eventually to readjustments of the instruments.

Conclusion

PCPs play an important role in everyday life for personal hygiene and wellness. However, it must be questioned whether the benefits outweigh any negative health and environmental effects. Furthermore, public awareness is low in regard to the hidden costs to human health or the environment due to their hazardous ingredients. Only a minority are informed of these risks (e.g., producers, medical doctors specialized in allergies, patients, environmentalists, or scientists working in this field). Therefore, there is an urgent need for how risks are communicated and the comprehension of this information to be improved for consumers (see 'Box: study highlights' section).

Several recommendations were presented for improving RC and reducing the risks posed by PCPs. Efficient RC and risk mitigation would not only reduce the number of people suffering from negative health effects but they also would help save costs for the health care systems and environmental remediation. They should be implemented as an integrated management strategy rather than focusing on only one approach to improve the situation. The ingredient lists on the containers of PCPs give valuable information for people who need or want to avoid certain ingredients. However, for the general

consumers, the list of ingredients cannot be regarded as an effective RC method. 'Read this!' does not guarantee the users' safety.

Abbreviations

CLP: Regulation on Classification, Labelling and Packaging; DAAB: Deutscher Allergie- und Asthmabund; ECHA: European Chemicals Agency; HHCB: 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylindeno(5,6-c)pyran (= Galaxolide); ICCR: International Cooperation on Cosmetic Regulation; INCI: Inventory and a common nomenclature of ingredients employed in cosmetic products; OTNE: 1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthylethanone; PCPs: personal care products; RC: risk communication; REACH: Registration, Evaluation, and Authorization of Chemicals; SA: South Africa.

Competing interests

Both authors declare no competing interests, neither financial nor otherwise.

Authors' contributions

UK and HR drafted the manuscript together. Both authors read and approved the final manuscript.

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References

1. European Commission: Regulation (EC) No. 1223/2009 of the European parliament and the council of 30 November 2009 on cosmetic products. *Off J Eur Commun* L342:59, 1–151. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF>.
2. Government Gazette: South African act no. 39 of 2007: foodstuffs, cosmetics and disinfectants amendment act. In *Government Gazette, Republic of South Africa*, Vol. 512 no. 30022. Pretoria:2008.
3. European Chemicals Agency: Guidance on the communication of information on the risks and safe use of chemicals. version 1. ECHA-2010-G-21-EN. Helsinki. <http://echa.europa.eu>.
4. United Nations Globally Harmonized System of Classification and Labelling of Chemicals (UN GHS). http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html.
5. Rother H-A, London L: Classification and labeling of chemicals: new globally harmonized system (GHS). *Encyclopaedia of Pest Management* 2008, 1(1):1–6.
6. Damalas CA, Eleftherohorinos IG: Pesticide exposure, safety issues, and risk assessment indicators. *Int J Environ Res Public Health* 2011, 8:1402–1419. doi:10.3390/ijerph8051402.
7. Noiesen E, Munk MD, Larsen K, Johansen JD, Agner T: Difficulties in avoiding exposure to allergens in cosmetics. *Contact Dermatitis* 2007, 57:105–109.
8. Lysdal SH, Johansen JD: Fragrance contact allergic patients: strategies for use of cosmetic products and perceived impact on life situation. *Contact Dermatitis* 2009, 61:320–324.
9. Oritz KJ, Yiannias JA: Contact dermatitis to cosmetics, fragrances, and botanicals. *Dermatol Ther* 2004, 17:264–271.
10. Dodson RE, Nishioka M, Standley LJ, Perovich LJ, Brody JG, Rudel RA: Endocrine disruptors and asthma-associated chemicals in consumer products. *Env Health Persp* 2012, 120(7):935–943.
11. Oishi S: Effects of propyl paraben on the male reproductive system. *Food Chem Toxicol* 2002, 23(40):1807–1813.
12. European Commission DG Environment: Endocrine Disruptors: Study on Gathering Information on 435 Substances with Insufficient Data. Final Report, GB Delft: RPS-BKH Consultants; 2002.
13. Schlumpf M, Schmid P, Durrer S, Conscience M, Maerker K, Henseler M, Gruetter M, Herzog I, Reolon S, Ceccatelli R, Faass O, Stutz E, Jarry H, Wuttke W, Lichtensteiger W: Endocrine activity and developmental toxicity of cosmetic UV filters—an update. *Toxicology* 2004, 35(205):113–122.
14. Orton DI, Wilkinson JD: Cosmetic allergy: incidence, diagnosis, and management. *Am J Clin Dermatol* 2004, 5(5):327–337.

15. Buckley DA: **Fragrance ingredient labelling in products on sale in the U.K.** *British J of Dermatology* 2007, **157**:295–300.
16. Schnuch A, Uter W, Geier J, Gefeller O: **Epidemiology of contact allergy: an estimation of morbidity employing the clinical epidemiology and drug utilisation research (CE-DUR) approach.** *Contact Dermatitis* 2002, **47**:32–39.
17. Schnuch A, Lessmann H, Geier J, Frosch PJ, Uter W: **Contact allergy to fragrances: frequencies of sensitization from 1996 to 2002. Results of the IVDK.** *Contact Dermatitis* 2004, **50**(2):65–76.
18. Schnuch A, Uter W, Geier J, Lessmann H, Frosch P: **Sensitization to 26 allergens to be labelled according to current European regulation: results of the IVDK and review of the literature.** *Contact Dermatitis* 2007, **57**:1–10.
19. Heisterberg MV, Menné T, Andersen KE, Avnstorp C, Kristensen B, Kristensen O, Kaaber K, Laurberg G, Nielsen NH, Sommerlund M, Thormann J, Veien NK, Vissing S, Johansen JD: **Deodorants are the leading cause of allergic contact dermatitis to fragrance ingredients.** *Contact Dermatitis* 2011, **64**(5):258–264.
20. Ormond G, Nieuwenhuijsen MJ, Nelson P, Toledano MB, Iszatt N, Geneletti S, Elliott P: **Endocrine disruptors in the workplace, hair spray, folate supplementation, and risk of hypospadias: case-control study.** *Environ Health Perspect* 2008, **118**(10):1–32.
21. Lundov MD, Moesby L, Zachariae C, Johansen JD: **Contamination versus preservation of cosmetics: a review on legislation, usage, infections, and contact allergy.** *Contact Dermatitis* 2009, **60**:70–78.
22. Yazar K, Boman A, Lidén C: **Potent skin sensitizers in oxidative hair dye products on the Swedish market.** *Contact Dermatitis* 2009, **61**:269–275.
23. Yazar K, Johnsson S, Lind M-L, Boman A, Lidén C: **Preservatives and fragrances in selected consumer-available cosmetics and detergents.** *Contact Dermatitis* 2010, **64**:265–272.
24. Yazar K, Boman A, Lidén C: **p-Phenylenediamine and other hair dye sensitizers in Spain.** *Contact Dermatitis* 2011, **66**:27–32.
25. Scheinman PL: **Prevalence of fragrance allergy.** *Dermatology* 2002, **205**:98–102.
26. Klaschka U: **Dangerous cosmetics - criteria for classification, labelling and packaging (EC 1272/2008) applied to personal care products.** *Env Sci Eur* 2012, **24**:37. doi:10.1186/2190-4715-24-37 URL: http://www.enveurope.com/content/24/1/37.
27. **C&L inventory.** [http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database]
28. Hutter H-P, Wallnen P, Moshhammer H, Hartl W, Sattelberger R, Lorbeer G, Kundi M: **Synthetic musk in blood of healthy young adults: relationship to cosmetic use.** *Sci Total Environ* 2009, **407**:4821–4825.
29. Donovan M, Tiwary CM, Axelrod D, Sasco AJ, Jones L, Hajek R, Sauber E, Kuo J, Davis DL: **Personal care products that contain estrogens or xenoestrogens may increase breast cancer risk.** *Med Hypotheses* 2007, **68**(4):756–766.
30. Russ K: **Health effects of personal care products – a review of the evidence.** *Nurs Womens Health* 2009, **13**(5):392–401.
31. Lorenz C, von Goetz N, Scheringer M, Wormuth M, Hungerbühler K: **Potential exposure of German consumers to engineered nanoparticles in cosmetics and personal care products.** *Nanotoxicology* 2011, **5**:12–29.
32. Grandjean P, Bellinger D, Bergman A, Cordier S, Davey-Smith G, Eskenazi B, Gee D, Gray K, Hanson M, van den Hazel P, Heindel JJ, Heinzow B, Hertz-Picciotto I, Hu H, Huang TT, Jensen TK, Landrigan PJ, McMillen IC, Murata K, Ritz B, Schoeters G, Skakkebaek NE, Skerfving S, Weihe P: **The Faroes statement: human health effects of developmental exposure to chemicals in our environment.** *Basic Clin Pharmacol Toxicol* 2007, **102**(2):73–75. doi:10.1111/j.1742-7843.2007.00114.x.
33. Poulsen PB, Schmidt A: **A survey and health assessment of cosmetic products for children In Danish Ministry of the Environment: Survey of Chemical Substances in Consumer Products, Volume 88.** 2007.
34. Horn T, Elliott D, Johnson A: **Personal care product survey.** Survey Research Lab Portland State University; 2011.
35. Jones-Lepp TL, Stevens R: **Pharmaceuticals and personal care products in biosolids/sewage sludge: the interface between analytical chemistry and regulation.** *Anal Bioanal Chem* 2007, **387**(4):1173–1183.
36. Boxall ABA, Rudd MA, Brooks BW, Caldwell DJ, Choi K, Hickmann S, Innes E, Ostapik K, Staveley JP, Verslycke T, Ankley GT, Beazley KF, Belanger SE, Berninger JP, Carriquiriborde P, Coors A, Deleo PC, Dyer SD, Ericson JF, Gagné F, Giesy JP, Gouin T, Hallstrom L, Karlsson MV, Larsson DG, Lazorchak JM, Mastrocco F, McLaughlin A, McMaster ME, Meyerhoff RD, et al: **Pharmaceuticals and personal care products in the environment: what are the big questions?** *Environ Health Perspect* 2012, **120**:1221–1229.
37. Corcoran J, Winter MJ, Tyler CR: **Pharmaceuticals in the aquatic environment: a critical review of the evidence for health effects in fish.** *Crit Rev Toxicol* 2010, **40**(4):287–304.
38. Ternes AT, Knacker T, Oehlmann J: **Körperpflegemittel in der aquatischen Umwelt: Eine bisher vernachlässigte Stoffgruppe.** *UWSZ-Z Umweltchem Ökotox* 2003, **15**(3):169–180.
39. Ternes TA, Joss A, Siegrist H: **Scrutinizing pharmaceuticals and personal care products in wastewater treatment.** *Environ Sci Technol* 2004, **38**(20):392A–399A.
40. Onesios KM, Yu JT, Bouwer EJ: **Biodegradation and removal of pharmaceuticals and personal care products in treatment systems: a review.** *Biodegradation* 2009, **20**:441–466.
41. Ramirez AJ, Brain RA, Usenko S, Mottaleb MA, O'Donnell JG, Stahl LL, Wathen JB, Snyder BD, Pitt JL, Perez-Hurtado P, Dobbins LL, Brooks BW, Chambliss CK: **Occurrence of pharmaceuticals and personal care products in fish: results of a national pilot study in the United States.** *Environ Toxicol Chem* 2009, **28**(12):2587–2597.
42. OSPARCommission: **OSPAR Background document on Musk Xylene and other musks.** In *Hazardous Substances Series*. London; 2004.
43. Rimkus GG: **Synthetic musk fragrances in the environment.** In *The Handbook of Environmental Chemistry*. Heidelberg: Springer; 2004:338.
44. Klaschka U, Carsten Von Der Ohe P, Bschorer A, Krezmer S, Sengl M, Letzel M: **Occurrences and potential risks of 16 fragrances in five German sewage treatment plants and their receiving waters.** *Env Sci & Pollut Res* 2013, **20**(4):2456–2471. doi:10.1007/s11356-012-1120-9 http://rd.springer.com/article/10.1007/s11356-012-1120-9.
45. Rother H-A: **Challenges in pesticide risk communication.** In *Encyclopedia of Environmental Health*. Edited by Nriagu Jerome O. New York: Elsevier; 2011:566–575.
46. Rother H-A: **Researching pesticide risk communication efficacy for South African farm workers.** *Occupational Health Southern Africa* 2005, **11**(3):20–26.
47. Rohrmann B: **A socio-psychological model for analyzing risk communication processes.** *Australasia J Disaster* 2000, **2**. http://www.massey.ac.nz/~trauma/issues/2000-2/rohrmann.htm.
48. Bennett P, Calman K: **Risk Communication and Public Health.** Britain, Oxford: Oxford University Press; 1999.
49. Fischhoff B: **Risk perception and risk communication unplugged: twenty years of process.** *Risk Anal* 1995, **15**:137–145.
50. Chess C: **Organizational theory and the stages of risk communication.** *Risk Anal* 2001, **21**(1):179–188.
51. OECD: **OECD Guidance document on risk communication for chemical risk management.** Paris; 2002. ENV/JM/MONO(2002)18. JT00129938.
52. ECHA: **Regulation (EC) No 1907/2006 Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).** Helsinki; 2006.
53. **Regulation (EC) No 1272/2008 of the European parliament and of the council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing directive 67/548/EEC and 1999/45/EC and amending regulation (EC) No 1907/2006.** [http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008R1272:en:NOT]
54. Pauwels M, Rogiers V: **Safety evaluation of cosmetics in the EU reality and challenges for the toxicologist.** *Toxicol Lett* 2004, **151**:7–17.
55. Bureau Européen des Unions de Consommateurs: **Cosmetic Products Should not Harm. BEUC Position on the Commission Proposal for a Regulation on Cosmetics.** Bruxelles; 2008.
56. Pauwels M, Rogiers V: **EU legislation affecting safety data availability of cosmetic ingredients.** *Reg Tox and Pharmacology* 2007, **49**:308–315.
57. De Groot R, Brekelmans P, Herremans J, Meulenbelt J: **The changes in hazard classification and product notification procedures of the new European CLP and cosmetics regulations.** *Clin Toxicol* 2010, **48**(1):28–33.
58. Nohynek GJ, Antignac E, Re T, Toutain H: **Safety assessment of personal care products/cosmetics and their ingredients.** *Toxicol Appl Pharmacol* 2010, **243**:239–259.
59. **Commission decision 96/335/EC of 8 May 1996 establishing an inventory and a common nomenclature of ingredients employed in cosmetic products.** *Off J L* 1996, **132**:1–684. [http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996D0335:EN:HTML]
60. **European Parliament and European Council: Directive 2003/15/EC of the European Parliament and of the Council of 27 Amending council directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products.** *Off J Eur Union* 2003, **66**:26–35.

61. Klaschka U: **Risk management by labelling 26 fragrances? Evaluation of article 10 (1) of the seventh amendment (guideline 2003/15/EC) of the cosmetic directive.** *J Hyg Environ Health* 2010, **213**:308–320.
62. South African Bureau of Standards Division: *Ingredient Labelling of Cosmetic Products. South African national Standard: SANS 98:2012.* Pretoria, South Africa; 2012. ISBN 978-0-626-26984-5.
63. Klaschka U: **Warum sind shampoos frei von warnhinweisen?** *Nachrichten aus der Chemie* 2013, **64**:530–532.
64. Klaschka U: **The hazard communication of contact allergens must be improved.** *Integr Environ Assess Manag* 2013, **9**(3):358–362. doi:10.1002/ieam.1397.
65. ICCR: *International cooperation on cosmetic regulation (ICCR) principles of cosmetic product safety assessment.* ICCR Report. May 25, 2011. http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/iccr5_safety_en.pdf [accessed 28 July, 2013].
66. ECHA: *Special Eurobarometer 360: Consumer Understanding of Labels and the Safe Use of Chemicals.* Helsinki; 2011. http://ec.europa.eu/public_opinion/index_en.htm.
67. ECHA: *Communication on the Safe Use of Chemicals: Study on the Communication of Information to the General Public.* Helsinki; 2012. ECHA-12-A-01-EN.
68. European Parliament and European Council: **Council directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances:** off J P 196, 16/8/1967, as amended by commission directive 2001/59/EC of 6 august 2001 adapting to technical progress for the 28th time council directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. *Off J L* 2001, **225**. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31967L0548:en:NOT>.
69. Rother H-A: **South African farm workers' interpretation of risk assessment data expressed as pictograms on pesticide labels.** *Environ Res* 2008, **108**:419–427.
70. Morgan MG, Fischhoff B, Bostrom A, Atman CJ: *Risk communication: a mental models approach.* Cambridge: Cambridge University Press; 2001.
71. Nardelli A, Drieghe J, Claes L, Boey L, Goossens A: **Fragrance allergens in 'specific' cosmetic products.** *Contact Dermatitis* 2011, **64**(4):212–219.
72. Steinemann AC, MacGregor IC, Gordon SM, Gallagher LG, Davis AL, Ribeiro DS, Wallace LA: **Fragranced consumer products: chemicals emitted, ingredients unlisted.** *Environ Impact Assess Rev* 2010, **31**:328–333. doi:10.1016/j.eiar.2010.08.002.
73. Rother HA: *Risk perception, risk communication, and the effectiveness of pesticide labels in communicating hazards to south African farm workers.* Ph.D dissertation. Michigan: Michigan State University; 2005.
74. Renn O, Benighaus C: **Perception of technological risk: insights from research and lessons for risk communication and management.** *J Risk Res* 2013, **16**:3–4. 293–313.
75. Luhmann N: **Technology, environment, and social risk: a systems perspective.** *Industrial Crisis Quarterly* 1990, **4**:223–231.
76. Molander L, Breitholtz M, Andersson PL, Rybacka A, Rudén C: **Are chemicals in articles an obstacle for reaching environmental goals? – Missing links in EU chemical management.** *Sci Total Environ* 2012, **435–436**:280–289.
77. Hansson SO, Molander L, Rudén C: **The substitution principle.** *Regul Toxicol Pharmacol* 2011, **59**:454–460.
78. Rastogi SC, Johansen JD: **Significant exposures to isoeugenol derivatives in perfumes.** *Contact Dermatitis* 2008, **58**:278–281.
79. Tanaka S, Royds C, Buckley D, Basketter DA, Goossens A, Bruze M, Svedman C, Menné T, Johansen JD, White IR, McFadden JP: **Contact allergy to isoeugenol and its derivatives: problems with allergen substitution.** *Contact Dermatitis* 2004, **51**:288–291.
80. Boelhouwer E, Davis J, Franco-Watkins A, Dorris N, Lungu C: **Comprehension of hazard communication: effects of pictograms on safety data sheets and labels.** *J Safety Res* 2013, **46**:145–155. <http://dx.doi.org/10.1016/j.jsr.2013.06.001>.
81. Riley DM, Fischhoff B, Small MJ, Fischbeck P: **Evaluating the effectiveness of risk-reduction strategies for consumer chemical products.** *Risk Anal* 2001, **21**(2):357–369.
82. Rother A, London L: *Field training on comprehensibility of chemical hazard communication for workers and the public in South Africa (Pilot phase).* Geneva: UNITAR; 2004.
83. European Parliament and European Council: **Directive 2001/37/EC of the European parliament and of the council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the member States concerning the manufacture, presentation and sale of tobacco products.**
84. Parliament of Australia: *Australian Tobacco Plain Packaging Bill.* 2011: C2011A00148.
85. Johansen JD, Frosch PJ, Lepoittevin JP: *Contact dermatitis.* Heidelberg Dordrecht London NewYork: Springer; 2011:553.
86. Klaschka U: **Allergene Duftstoffe: welche kosmetikprodukte sind empfehlenswert?** *Umweltwissenschaften und Schadstoffforschung* 2010, **22**:168–176.
87. Steinemann AC: **Fragranced consumer products and undisclosed ingredients.** *Environm Impact assess Rev* 2009, **29**(1):32–38.

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